K024281

FEB 2 4 2003

Wako Diagnostics
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

510(K) Summary of Safety and Effectiveness

The Wako L-Type Glu 2 test is an in vitro assay for the quantitative determination of glucose in serum, plasma or urine.

Summary:
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus. There are several methods used for the determination of glucose level. In the past, colorimetric or oxidation-reduction methods were used. The Wako L-Type Glu 2 is a highly specific enzymatic method utilizing hexokinase (HK) and glucose-6-phosphate dehydrogens (G-6-PDH) combinationally.

Principle:
When a sample is mixed with Enzyme and ATP, the glucose in the sample yields glucose-6-phosphate (G-6-P) and adenosine-5'-diphosphate (ADP) by HK. G-6-P is conversed to 6-phosphogluconic acid by G-6-PDH in the presence of NAD and at the same time, NAD is reduced to NADH. By measuring the increase in the absorbance at 340 nm due to the reduction of NAD, glucose concentration in the sample is determined.

The safety and effectiveness of the Wako L-type Glu 2 is demonstrated by its substantial equivalency to Wako

Both test systems are used to measure glucose in serum, plasma or urine.

References:
1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Hengartner, H and Zuber, H.: FEBS LETTERS, 37, 212-216 (1973).
3. DG Klinische Chemie Mitteilungen 26 (1995) page 5.
4. Chan, A.Y.W., Swaminathan, R., Cockram, C.S.:Clin.Chem.,35:315-317,1989.

Tonya Mallory, Sr. Manager Wako Diagnostics
September 22, 1999
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Tonya Mallory
Senior Manager
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237

FEB 2 4 2003

Re: k024281
Trade/Device Name: Wako L-Type Glucose 2
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: December 20, 2002
Received: December 23, 2002

Dear Ms. Mallory:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use:

A Glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Proprietary Name: Wako L-Type Glucose 2

Established Registration Number: 1627434

Premarket Notification 510 (k) Number: K024281

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024281